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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant(s) No.	Applicant(s)	
	10/764,370	VAN MEETEREN, NORMAN	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4152005, 12062005, 7072005</u> | 6) <input checked="" type="checkbox"/> Other: <u>Request under 37 CFR 1.105</u> |

DETAILED ACTION

Claim Objections

1. Claims 1, 6, 22, 23, 28 are objected to for containing a blank line where the ATCC accession number should be. Appropriate correction is required.

Further in claim 28: in line 2, the term, "into" should be replaced with --in--, as the method is for modifying the fatty acid or carbohydrate metabolism of SG5322NRR.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 6, 22, 23, 24, 28, and 29: the claims are indefinite for the recitation, "SG5322NRR". This is an arbitrarily assigned name for a soybean variety. It does not define any traits possessed by the variety. This name can also be changed or arbitrarily assigned to any other plant line. Inclusion of the ATCC accession number into claims 1, 6, 22, 23, and 28 will obviate the rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn towards seed of soybean line SG5322NRR. Claims 2-29 are drawn towards a soybean plant produced by growing said seed, methods comprising using soybean plant SG5322NRR, hybrid soybean seeds and plants having SG5322NRR as a parent, and products produced from the methods.

The claimed seed of soybean variety SG5322NRR is essential to the claimed invention. It must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification discloses some traits expressed by this plant line (pages 9-10, paragraphs [0054]-[0069], Table 1). However, the specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. A deposit of the seeds of inbred soybean line SG5322NRR with an acceptable depository is required. Page 29 of the specification indicates that a deposit of said seed with the ATCC has not yet been made.

If a deposit will be made under the terms of the Budapest Treaty, then a statement, affidavit or declaration by Applicants, or a statement by an attorney of record over his or her

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signature and registration number, or someone empowered to make such a statement, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained. See 37 CFR 1.801-1.809.

If a deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make the same, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

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4. Claims 23-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods of introducing a desired trait or modifying fatty acid or carbohydrate metabolism in soybean line SG5322NRR wherein fourth or higher backcross progeny plants are selected, does not reasonably provide enablement for the claimed methods when fewer than a fourth backcross progeny plants are produced. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards methods of introducing a desired trait or modifying fatty acid or carbohydrate metabolism in soybean line SG5322NRR, comprising crossing said soybean line with a soybean line comprising one of the recited traits, or one of the recited nucleic acid molecules, selecting progeny plants comprising the trait or nucleic acid molecule, crossing them with SG5322NRR to produce backcross progeny plants, selecting backcross progeny plants having the desired trait or nucleic acid molecule and characteristics of SG5322NRR listed in Table 1, repeating the crossing step with SG5322NRR one or more times to produce selected second or higher backcross progeny plants comprising the desired trait or nucleic acid molecule and all the characteristics of SG5322NRR listed in Table 1 at the 5% significance level; and plants produced by said methods.

The specification discusses introducing single genes into soybean plants by crossing a first variety of interest with another “donor” parent plant, which contains the single gene that is to be introduced into the first variety. The progeny of that cross is then backcrossed with the first variety. The progeny of the backcross gets backcrossed with the first variety several more times, until a plant is recovered that has essentially all of the desired morphological and

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physiological traits of the original, first variety in addition to the trait (single gene) transferred from the donor parent (specification, pages 24-25).

The practice of crossing two plant varieties, each expressing two different desired traits for example, to obtain a single variety that expresses both desired traits is well established. However, the specification does not teach any SG5322NRR plants produced by the claimed methods, wherein the resultant plant retains all the morphological and physiological traits of Table 1 in addition to exhibiting the introduced single trait, wherein only three or fewer backcross and selection steps are performed. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a plant that retains several of the original traits, in addition with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single locus conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the

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various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Narvel et al. (Crop Sci., 2001, Vol. 41, pages 1931-1939) teach that soybean breeding programs have failed to yield cultivars comprising an introgressed locus conferring insect resistance due to factors such as inadequate resistance levels, inferior seed yield, poor agronomic characteristics, and retention of undesirable alleles from the donor plant, affecting any number of traits because of tight linkage with the insect resistance alleles (page 1931). Narvel et al. also assert that linkage drag is often regarded as a limitation to the use of nondomesticated germplasm, and that the extent of linkage drag depends on numerous variables, such as population size, the number of meiotic generations before selection is applied, and the genomic location of the locus of interest (page 1937). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of backcross conversions taught in the prior art, in order to yield the claimed plants which are to differ from SG5322NRR in only a single locus and trait, or even a single gene. It is suggested that claims 23 and 28 be amended to indicate in step (e) that steps (c) and (d) are repeated three or more times in succession, to produced selected fourth or higher backcross progeny plants.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shannon (U.S. Patent No. 6,013,865, issued January 11, 2000).

The claims are broadly drawn towards seed of soybean line SG5322NRR; a soybean plant or a part thereof produced by growing said seed; tissue culture of regenerable cells produced from said plant; hybrid soybean seeds and plants produced by a method comprising crossing said plant with a different soybean plant.

Shannon teaches seeds and plants of soybean variety 93-13946. It appears that this variety is the same as instant soybean variety SG5322NRR. Many traits listed in the variety description information for 93-13946 in columns 5-6, such as black hilum color, purple flower color, tan pod color, tawny pubescence color, determinate plant habit, maturity group V, are also possessed by SG5322NRR. Both varieties show resistance to stem canker, races 3 and 14 of soybean cyst nematode, and glyphosate herbicide, and susceptibility to southern root knot and peanut root knot nematodes. Other traits, such as plant seed size, relative maturity, yield, are affected by environmental effects on plant growth. Still, both cultivars show very high or excellent yield potential (instant specification, paragraph [0054]; '865, col. 5, lines 14-15). The

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patent is silent regarding resistance or susceptibility to races 2 and 4 of phytophthora root rot and Javanese nematode. The USPTO does not have sufficient facts to determine if all other unrecited Mendelian traits possessed by 93-13946 and SG5322NRR are the same, or if their genomes are the same. The USPTO cannot conclude that the subject matter of the claims would have been obvious since it cannot determine whether the genomes of the soybean varieties differ. The USPTO/examiner is not in a position to make either a conclusion of “inherency/anticipation” or “obviousness” since the record does not allow one to determine if and how the instantly claimed subject matter differs from the prior art. Accordingly, the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977). Shannon teaches crossing 93-13946 with other soybean plants, hybrid soybean seeds and plants produced by the cross; tissue culture of regenerable cells of plant 93-13946, and regenerating soybean plants from the tissue culture, wherein the regenerated plant has all of the morphological and physiological characteristics of 93-13946; (claims). It also would have been obvious to one of ordinary skill in the art to produce protoplasts or tissue culture from tissues such as leaf, pollen, embryo, root, root tip, anther, pistil, flower, seed, pod, or stem, as production of such cultures are well-established in the art, and as Shannon indicates that the term “plant” includes protoplasts and tissue culture cells that can be regenerated, and plant cells in intact parts such as pollen, flower, seeds, pod, leaves, stem (col. 4, lines 34-40).

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6. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shannon (U.S. Patent No. 6,013,865, issued January 11, 2000) in combination with Schultze (U.S. Patent No. 6,838,597).

The claims are broadly drawn towards seed of soybean line SG5322NRR; a soybean plant or a part thereof produced by growing said seed; tissue culture of regenerable cells produced from said plant; hybrid soybean seeds and plants produced by a method comprising crossing said plant with a different soybean plant; method of introducing a transgene conferring male sterility or herbicide, disease, or insect resistance, or modification of carbohydrate or fatty acid metabolism into SG5322NRR; methods of introducing a desired trait or modifying fatty acid or carbohydrate metabolism in soybean line SG5322NRR, comprising crossing said soybean line with a soybean line comprising one of the recited traits, or one of the recited nucleic acid molecules, selecting progeny plants comprising the trait or nucleic acid molecule, crossing them with SG5322NRR to produce backcross progeny plants, selecting backcross progeny plants having the desired trait or nucleic acid molecule and characteristics of SG5322NRR listed in Table 1, repeating the crossing step with SG5322NRR one or more times to produced selected second or higher backcross progeny plants comprising the desired trait or nucleic acid molecule and all the characteristics of SG5322NRR listed in Table 1 at the 5% significance level; and plants produced by said methods.

Shannon et al. is discussed above.

Shannon et al. do not teach method of transformation of soybean or introducing the particular recited traits of the instant claims into a soybean plant.

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Schultze teaches transforming soybean plants with transgenes that confer male sterility or herbicide, disease, or insect resistance, or modification of carbohydrate or fatty acid metabolism. The herbicide includes, imidazolinone, sulfonylurea, glyphosate, glufosinate, phosphinothricin, triazine, and benzonitrile; the insect resistance gene can be a *B. thuringiensis* endotoxin; the fatty acid or carbohydrate metabolism modifying gene can encode stearyl-ACP desaturase, fructosyltransferase, levansucrase, α -amylase, invertase, and starch branching enzyme; and a method of introducing a trait into these traits into a soybean plant comprising crossing with a soybean plant comprising the trait and backcrossing to the original parent (claims; col. 11, line 66 to col. 12, line 6; col. 13, line 52 to col. 14, line 51; col. 16, line 10 to col. 17, line 6).

It would have been obvious and within the scope of one of ordinary skill in the art to modify soybean cultivar 93-13946, which appears to be the same as SG5322NRR as discuss above, to transforming it with a transgene conferring male sterility or herbicide, disease, or insect resistance, or modification of carbohydrate or fatty acid metabolism. One would have been motivated to do so given their obvious agronomic advantages. It also would have been obvious to introduce a desired trait, including those recited in the instant claims 23 and 28, into the soybean plant of Shannon, following for example the backcrossing protocol and suggestion of desirable traits as taught by Schultze. One would have been obvious repeatedly backcross the progeny plants comprising the desired trait several times with 93-13946, and in order to obtain plants have the desired traits and any desirable traits already possess by 93-13946, which are presented in the Variety Description Information in col. 7 of Shannon. One would have been motivated to use such a method to introduce further desirable traits into the plant, to avoid possible complications of transformation, such as position effects. One also would have been

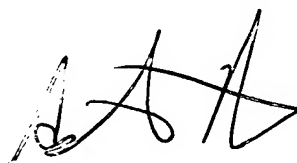
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motivated to screen the final backcross progeny plants for the presence of the original traits at the 5% significance level, as it is these traits that are highlighted by Shannon as being desirable.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638

August 7, 2006

ATTACHMENT TO OFFICE ACTION

Request for Information under 37 CFR § 1.105

1. Applicant and the assignee of this application are required under 37 CFR § 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

2. This request is being made for the following reasons:

Applicant is claiming hybrid seed comprising at least 50% of the genome of soybean line SG5322NRR, and soybean plants produced in methods that comprise performing crosses with soybean plant SG5322NRR. However, the instant specification is silent about what starting materials and methods were used to produce soybean line SG5322NRR. The requested information is required to make a meaningful and complete search of the prior art.

3. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were (are) the original parental soybean lines used to produce soybean line SG5322NRR? Please supply all of the designations/denominations used for the original parental soybean lines and line SG5322NRR. Please supply information pertaining to the lineage of the original parental lines back to any publicly available varieties.

(ii) What method and method steps were used to produce soybean line SG5322NRR?

(iii) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, had any of said parental soybean lines or progeny therefrom been disclosed or made publicly available? If so, under what

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designation/denomination and under what conditions were said parental soybean lines or progeny disclosed or made publicly available and from when to when?

(iv) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, were any other soybean lines produced by said method using said original parental soybean lines, and if so, had said produced soybean lines been publicly available or sold? If so, under what designation/denomination and under what conditions were said other soybean lines disclosed or made publicly available and from when to when?

3. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please indicate where the relevant information can be found.

5. The fee and certification requirements of 37 CFR § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR § 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR § 1.105 are subject to the fee and certification requirements of 37 CFR § 1.97.

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6. The Applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR § 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

7. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER